Attorney Docket # 5434-16 Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Tom MINER, *et al.*
Serial No.: 10/768,760
Filed: January 29, 2004
For: Intravenous Delivery System

Examiner: Osinski, Bradley J.
Group Art: 4111

Mail Stop **Appeal Brief - Patents**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF

SIR:

This is in response to the Notice of Non-Compliant Appeal Brief dated January 11, 2010. In the Notice, the Office took the position that the section of the Appeal Brief entitled "Summary of the Claimed Subject Matter" was not in compliance with 37 C.F.R. § 41.37(c)(1)(v), in that the independent claims were discussed in groups, rather than individually. While traversing this objection as it is believed that the Appeal Brief as filed is in compliance with the rule as written, applicants submit herewith a revised "Summary of the Claimed Subject Matter" section of the Appeal Brief.

It is believed that no fees are due herewith. If any additional fees or charges are required in connection with this application, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The following summary of the invention is offered for the benefit of the Board and is taken from the specification. It is not intended to argue limitations not present in the claims, or to argue for the interpretation of any claim term that is different from, or more narrow than, the broadest reasonable interpretation of such term as it would be understood by one of ordinary skill in the art upon a full and fair reading of the specification.

The invention is directed to a system and method for delivering a solution to a patient through a self-priming intravenous (IV) delivery system, together with components and sub-assemblies of such systems and methods of using such systems. The invention as claimed in each independent claim is summarized individually below.

References to "page" and "line" are to the respective page and lines of the specification., and reference to "Fig. __" is to the indicated Figure of the drawings.

Independent Claim 1

Claim 1 is directed to a self-priming IV-solution delivery system **10** for intravenous delivery of a liquid medicament (or "solution") from a container **26** to a patient. (Fig. 1; page 11, lines 2-6). System **10** includes a coupling assembly **12** for conveying the solution from container **26** to a drip chamber **16**, from which it enters a conduit **20** from which it is, in turn, dispensed to the patient. (page 11, lines 9-12). Drip chamber **16** has a substantially transparent side wall **58** with an opening **60** formed therein, vertically displaced from the bottom **54** of drip chamber **16** by a predetermined amount **X** (Fig. 1; page 14, lines 8-9), and is filled by a vent plug **62** (Fig. 1; page 14, lines 12-14). Vent plug **62** is formed of material which allows displaced air from drip chamber **16** to exit drip chamber **16** to the surrounding atmosphere but which, upon contacting liquid, expands or swells to seal off opening **60**, thereby precluding the further passage of air

therethrough. (page 17, lines 4-8). Opening **60** is oriented so that air may pass therethrough in a direction transverse to the direction of the flow of drops of solution through drip chamber **16** (Fig. 1), thereby permitting the substantially unobstructed view of the drip of solution in drip chamber **16**. System **10** further includes a flow restriction device **24** for restricting the flow of solution through conduit **20**. (page 11, lines 10-12).

Restriction of the flow of solution through conduit **20** *via* flow restriction device **24** causes solution to fill up drip chamber **16** until the level of solution reaches level **X**, wetting vent plug **62** and sealing opening **60**. (page 17, lines 1-9).

Independent claim 22

Claim 22 is directed to a self-priming IV-solution delivery system **10** for intravenous delivery of a liquid medicament (or "solution") from a container **26** to a patient (Fig. 1; page 11, lines 2-6), and contains all of the elements of claim 1, namely:

System **10** includes a coupling assembly **12** for conveying the solution from container **26** to a drip chamber **16**, from which it enters a conduit **20** from which it is, in turn, dispensed to the patient. (page 11, lines 9-12). Drip chamber **16** has a substantially transparent side wall **58** with an opening **60** formed therein, vertically displaced from the bottom **54** of drip chamber **16** by a predetermined amount **X** (Fig. 1; page 14, lines 8-9), and is filled by a vent plug **62** (Fig. 1; page 14, lines 12-14). Vent plug **62** is formed of material which allows displaced air from drip chamber **16** to exit drip chamber **16** to the surrounding atmosphere but which, upon contacting liquid, expands or swells to seal off opening **60**, thereby precluding the further passage of air therethrough. (page 17, lines 4-8). Opening **60** is oriented so that air may pass therethrough in a direction transverse to the direction of the flow of drops of solution through drip chamber **16** (Fig. 1), thereby permitting the substantially unobstructed view of the drip of solution in drip

chamber **16**. System **10** further includes a flow restriction device **24** for restricting the flow of solution through conduit **20**. (page 11, lines 10-12).

Restriction of the flow of solution through conduit **20** *via* flow restriction device **24** causes solution to fill up drip chamber **16** until the level of solution reaches level **X**, wetting vent plug **62** and sealing opening **60**. (page 17, lines 1-9).

The system of Claim 22 further includes a splash guard **76** formed in, or attached to, side wall **58** of drip chamber **16**, to prevent the splashing of solution onto vent plug **62** before the level of solution in drip chamber **16** reaches level **X**. (page 19, lines 6-11).

Independent claim 24

Claim 24 is directed to an improvement in an IV solution delivery system **10**.

System **10** includes a coupling assembly **12** for conveying the solution from container **26** to a drip chamber **16**, from which it enters a conduit **20** from which it is, in turn, dispensed to the patient. (page 11, lines 9-12). Drip chamber **16** has a substantially transparent side wall **58**. (page 13, lines 19-21).

The improvement provides self-priming of system **10**, and comprises providing side wall **58** with an opening **60** formed therein. Opening **60** is vertically displaced from the bottom **54** of drip chamber **16** by a predetermined amount **X** (Fig. 1; page 14, lines 8-9), and is filled by a vent plug **62** (Fig. 1; page 14, lines 12-14). Vent plug **62** is formed of material which allows displaced air from drip chamber **16** to exit drip chamber **16** to the surrounding atmosphere but which, upon contacting liquid, expands or swells to seal off opening **60**, thereby precluding the further passage of air therethrough. (page 17, lines 4-8). Opening **60** is oriented so that air may pass therethrough in a direction transverse to the direction of the flow of drops of solution through drip chamber **16** (Fig. 1), thereby permitting the substantially unobstructed view of the drip of

solution in drip chamber **16**. System **10** further includes a flow restriction device **24** for restricting the flow of solution through conduit **20**. (page 11, lines 10-12).

Restriction of the flow of solution through conduit **20** *via* flow restriction device **24** causes solution to fill up drip chamber **16** until the level of solution reaches level **X**, wetting vent plug **62** and sealing opening **60**. (page 17, lines 1-9).

Independent claim 31

Claim 31 is directed to a drip chamber **16** for use in an IV delivery system **10**. System **10** includes a coupling assembly **12** for conveying a solution from a container **26** to drip chamber **16**, from which it enters a conduit **20** from which it is, in turn, dispensed to the patient. (page 11, lines 9-12).

Drip chamber **16** has a substantially transparent side wall **58** (page 13, lines 19-21) with an opening **60** formed therein. (page 14, lines 7-9) Opening **60** is vertically displaced from the bottom **54** of drip chamber **16** by a predetermined amount **X** (Fig. 1; page 14, lines 8-9), and is filled by a vent plug **62** (Fig. 1; page 14, lines 12-14). Vent plug **62** is formed of material which allows displaced air from drip chamber **16** to exit drip chamber **16** to the surrounding atmosphere but which, upon contacting liquid, expands or swells to seal off opening **60**, thereby precluding the further passage of air therethrough. (page 17, lines 4-8). Opening **60** is oriented so that air may pass therethrough in a direction transverse to the direction of the flow of drops of solution through drip chamber **16** (Fig. 1), thereby permitting the substantially unobstructed view of the drip of solution in drip chamber **16**.

Independent claim 40

Claim 40 is directed to a drip chamber **16** for use in an IV delivery system **10**. System **10** includes a coupling assembly **12** for conveying a solution from a container **26** to drip chamber **16**, from which it enters a conduit **20** from which it is, in turn, dispensed to the patient. (page 11, lines 9-12).

Drip chamber **16** has a substantially transparent side wall **58** (page 13, lines 19-21) having two sections: a first section made of an impervious material and a second section **62'** of a wettable, sealable, material (Figs. 1a and 1b; page 14, lines 18-22) Second section **62'** is vertically displaced from the bottom **54** of drip chamber **16** (Figs. 1a and 1b; page 14, lines 18-22). The material of second section **62'** is formed of material which allows displaced air from drip chamber **16** to exit drip chamber **16** to the surrounding atmosphere but which, upon contacting liquid, expands or swells to seal off drip chamber **16**, thereby precluding the further passage of air therethrough. (page 17, lines 4-8). Second section **62'** is oriented so that air may pass therethrough in a direction transverse to the direction of the flow of drops of solution through drip chamber **16** (Fig. 1a), thereby permitting the substantially unobstructed view of the drip of solution in drip chamber **16**.

Independent claim 43

Claim 43 is directed to a solution delivery system **10** for delivering a solution from a container **26** to a patient. System **10** comprises: a coupling assembly **12** for coupling to container **26,** a conduit **20** for providing the solution to the patient (page 11, lines 2-9), means **24** for regulating a flow rate of solution from coupling assembly **12** to conduit **20** (page 15, lines 6-8) and a termination end cap **70** coupled to conduit **20** and having a vent **72** for restricting the flow of solution into conduit **20** and allowing air displaced by the flow of solution through

conduit **20** to escape through termination end cap **70** (page 15, lines 2-6). A wettable, sealable, termination end vent plug **74** allows air to escape from conduit **20** until it gets wet, at which point it seals conduit **20** preventing any solution from escaping therefrom. (page 18, lines 1-9).

Independent claim 49

Claim 49 is directed to a method of intravenous delivery of a solution from a container **26** to a patient. The method comprises the steps of placing container **26** at a height above the patient, attaching a coupling assembly **10** to container **26**, and coupling a drip chamber **16** to coupling assembly **12**. (page 8, lines 17-22).

Drip chamber **16** has a substantially transparent side wall **58** (page 13, lines 19-21) with an opening **60** formed therein. (page 14, lines 7-9) Opening **60** is filled by a vent plug **62** (Fig. 1; page 14, lines 12-14). Vent plug **62** is formed of material which allows displaced air from the drip chamber **16** to exit from drip chamber **16** to the surrounding atmosphere but which, upon contacting liquid, expands or swells to seal off opening **60**, thereby precluding the further passage of air therethrough. (page 17, lines 4-8). Opening **60** is oriented so that air may pass therethrough in a direction transverse to the direction of the flow of drops of solution through drip chamber **16** (Fig. 1), thereby permitting the substantially unobstructed view of the drip of solution in drip chamber **16**.

The method further comprises the steps of connecting a patient conduit **20** to drip chamber **16** and restricting the fluid flow in conduit **20** to allow a reservoir of the solution to form in drip chamber **16** and discontinuing the restriction when vent plug **62** is wetted.

Independent claim 55

Claim 55 is directed to a self-priming IV-solution delivery system **10** for intravenous delivery of a liquid medicament (or "solution") from a container **26** to a patient (Fig. 1; page 11, lines 2-6), and contains all of the elements of claim 1, namely:

System **10** includes a coupling assembly **12** for conveying the solution from container **26** to a drip chamber **16**, from which it enters a conduit **20** from which it is, in turn, dispensed to the patient. (page 11, lines 9-12). Drip chamber **16** has a substantially transparent side wall **58** with an opening **60** formed therein, vertically displaced from the bottom **54** of drip chamber **16** by a predetermined amount **X** (Fig. 1; page 14, lines 8-9), and is filled by a vent plug **62** (Fig. 1; page 14, lines 12-14). Vent plug **62** is formed of material which allows displaced air from drip chamber **16** to exit drip chamber **16** to the surrounding atmosphere but which, upon contacting liquid, expands or swells to seal off opening **60**, thereby precluding the further passage of air therethrough. (page 17, lines 4-8). Opening **60** is oriented so that air may pass therethrough in a direction transverse to the direction of the flow of drops of solution through drip chamber **16** (Fig. 1), thereby permitting the substantially unobstructed view of the drip of solution in drip chamber **16**. System **10** further includes a flow restriction device **24** for restricting the flow of solution through conduit **20**. (page 11, lines 10-12).

Restriction of the flow of solution through conduit **20** *via* flow restriction device **24** causes solution to fill up drip chamber **16** until the level of solution reaches level **X**, wetting vent plug **62** and sealing opening **60**. (page 17, lines 1-9).

System **10** further includes a termination end cap **70** at a termination end **22** of conduit **20**, termination end cap **70** includes a termination end vent **72** for venting air in conduit **20** before the solution is introduced into the patient. (page 15, lines 1-6). Termination end vent **72**

includes a termination end vent plug **74** which, when wetted, seals termination end vent **72**. (page 18, lines 3-15).

"Means plus function" limitation

Claim 43 includes a "regulating means" which is illustrated in the specification as knurled wheel **25**.

Discussion of the claimed subject matter

Dispensing medicament to a patient with n IV system is well-known, *per se*, and has certain well-known concerns. Among those concerns are the ability to monitor the speed at which the medicament is dispensed (the "flow rate") and the need to ensure that conduit **20** is free from entrained air bubbles, since permitting entrained air bubbles to be injected into the patient intravenously may lead to the formation of an air bubble ("embolus") in the patient, causing a stroke or death. Both of these concerns are addressed by the inventive drip chamber **16**.

Drip chamber **16** holds the solution after being dispensed from container **26,** and acts as a holding area, where the flow rate of the solution can be monitored by a dispensing professional, such as a nurse. Drip chambers are usually substantially transparent, to permit the monitoring of the flow rate.

Independent claims 1 (claims 2-21 and 54 depending therefrom), 22 (claim 23 depending therefrom) and 55 are directed to embodiments of the overall system. Independent claim 24 (claims 25-30 depending therefrom) is directed to an improvement in such a system, namely the location of an opening (as will be described below) in a drip chamber thereof. Independent claims 31 (claims 32-39 depending therefrom) and 40 (claims 41-42 depending therefrom) are directed to embodiments of the drip chamber used in the system. Independent claim 43 (claims 44-48, 52 and

53 depending therefrom) is directed to a solution delivery system. Independent claim 49 (claims 50-51 depending therefrom) is directed to a method of using the system.

For purposes of this Appeal, appellants argue that the invention as claimed in claims 1-42, and 49-55 is distinct from the prior art based upon the construction of a component of the overall system, namely drip chamber **16.** Drip chamber **16** is a claimed component of the overall system (independent claims 1, 22 and 55), is used in the claimed method (independent claim 49), and is also the subject of its own independent claims (independent claims 31 and 40). It is also a component found in dependent claims 52 and 53 which depend from system claim 43.

Understanding the invention will be simpler if placed in context. The overall system **10** is intended for the IV delivery of a liquid medicament (or "solution") from a container **26** to a patient (not shown). (Fig. 1; page 11. lines 2-6). In use, container **26** dispenses the solution into a drip chamber **16**, from which it enters a conduit **20** from which it is, in turn, dispensed to the patient. (page 11, lines 9-12). Dispensing medicament to a patient in this fashion is well-known, *per se*, and has certain well-known concerns. Among those concerns are the ability to monitor the speed at which the medicament is dispensed (the "flow rate") and the need to ensure that conduit **20** is free from entrained air bubbles, since permitting entrained air bubbles to be injected into the patient intravenously may lead to the formation of an air bubble ("embolus") in the patient, causing a stroke or death. Both of these concerns are addressed by the inventive drip chamber **16**.

Drip chamber **16** holds the solution after being dispensed from container **26,** and acts as a holding area, where the flow rate of the solution can be monitored by a dispensing professional, such as a nurse. Drip chambers are usually substantially transparent, to permit the monitoring of the flow rate.

Drip chamber **16** generally starts empty, and must therefore fill up to a desired level ("primed") so that a reservoir **64** forms in the bottom thereof. To allow drip chamber **16** to fill, a regulating means, such as knurled knob **25** is provided, so that the conduit which exits from drip chamber **16** may be closed. The rate of flow of the solution in the system is visually illustrated by the drops of the solution from the top of the chamber to the bottom (illustrated as drops **59** in the Drawings; page 12, lines 5-6). The more drops per second, the faster the flow of solution. Nurses can look at the rate of the drops to determine if the solution is being delivered at an appropriate rate to the patient. It is therefore important that the height of reservoir **64** be set at a level which is neither too high nor too low to allow for proper viewing. It is generally preferred that the height be approximately one-third (1/3) of the overall height of drip chamber **16**. (page 15, lines 12-13).

Those of ordinary skill in the art, therefore, must confront the problem of creating a reservoir of solution in the bottom of the drip chamber that is of a desired height to prevent the formation of air bubbles and yet provide a sufficient distance between the top of the chamber and the surface of the reservoir to allow for viewing of the drip rate. The priming of the system to create a reservoir of the desired height is thus of high importance.

In many prior art systems, the drip chambers are made of a resilient transparent material, to allow for manual priming by, for example, squeezing the drip chamber to force air out of the drip chamber, and then allowing the drip chamber to revert to its original shape, thereby drawing solution into the drip chamber at a faster rate than it will be dispensed, until a reservoir having a desired level of solution forms in the drip chamber. This, however, allows the "over-priming" of the drip chamber, so that the distance between the top of the drip chamber to the top of the reservoir of solution in the drip chamber may be too small, rendering it difficult to monitor the flow rate. Over-priming is to be avoided, but is a constant risk in manual systems, especially those in which

priming may be accomplished by the brute force method of squeezing and releasing a resilient drip chamber.

Another problem with existing IV systems is that when the drip chamber is squeezed to adjust the solution flow rate, the pressurized conditions in the drip chamber may cause the solution to flow into the drip chamber as a narrow stream at high velocity. As the high velocity liquid stream impinges the surface of the reservoir, bubbles become entrapped in the liquid reservoir, thus causing an air-bubble mixture to form. When this occurs, the user, usually a nurse, must perform the time-consuming task of purging the air bubbles from the drip chamber and from the conduit leading to the patient. This typically involves gently tapping the drip chamber and the conduit leading to the patient. If air bubbles are not purged, they may enter the patient and cause an embolism or other harmful effects. (page 5, lines 4-12).

Unwanted air bubbles may also form from a too-rapid filling of IV-solution into patient conduit **20** in infusion pump systems (*e.g.*, when no drip chamber is present). Such air bubbles form on the inside surface of the conduit and are typically removed by gently tapping the conduit, thereby causing them to dislodge, and then expelling them from an end of the conduit. (page 5, lines 13-16).

These problems are remedied in the system as claimed by the provision of an opening **60** in a side wall **58** of drip chamber **16** (page 14, lines 7-8), which opening **60** is set at a level **X** on side wall **58** that is at the level of solution that provides the desired height of reservoir **64** in drip chamber **16** (page 14, lines 8-9). Opening **60** is covered by a wettable, sealable, vent plug **62** (page 17, lines 4-8), which seals opening **60** when the level of solution reaches vent plug **62** (in opening **60**), and provides *self-priming* of the system, *i.e.*, priming to the desired level without intervention by the user. Prior to the solution reaching the level of vent plug **62**, air that is displaced from the

entering solution flows through opening **60**, allowing the level of solution to rise to the level of opening **60**. The volume of the solution filling the bottom of drip chamber **16** to form reservoir **64** displaces an equal volume of air in drip chamber **16** at the same rate as the rate of flow of solution into drip chamber **16**.

Once the solution reaches vent plug **62**, however, the liquid solution wets vent plug **62**, causing it to close, thereby sealing opening **60** (page 17, lines 4-8). Once opening **60** is sealed, the volume of air in drip chamber **16** above the height of reservoir **64** (as established by the placement of opening **60**) is fixed, thereby also fixing the height of the reservoir (page 17, lines 11-16). It is important to note that this configuration allows the automatic and precise setting of the height of reservoir **64** to the desired level without intervention from the user, and without the possibility of over-priming (page 17, lines 16-19). After the drip chamber is primed, knurled knob **25** may release the solution into the conduit to prime the conduit before the solution is ultimately dispensed to the patient. The priming of the conduit is described below in relation to the system of claims 43-48.

In the claimed invention, opening **60** is oriented in a direction transverse to the flow of drops **59** of solution in drip chamber **16** (see, *e.g.*, Fig. 1) so that transparent side wall **58** thereof is open to view from all sides and the rate of flow of the drops of solution may, therefore, be monitored without obstruction. The placement and orientation of opening **60** and vent plug **62** therefore permit the self-priming of the system with no intervention by the user, and yet allow for easy viewing of the flow rate from any vantage point.

This combination of features, namely the provision of a wettable vent plug in an opening oriented transverse to the flow of drops of medicament at the desired height of the reservoir, is

nowhere shown in the art, and would not be an obvious modification of the art applied by the Examiner, as discussed below.

The invention of claims 43-48, 52 and 53 is directed to a different portion of the overall system **10**, namely a termination end cap which is placed downstream of drip chamber **16** in conduit **20** near the patient.

To facilitate formation of reservoir **64** and, specifically, to prevent the medicament from draining into conduit **20** before reservoir **64** can be formed to a desired depth relative to drip chamber bottom **54**, liquid flow through conduit **20** must be obstructed so that the medicament level will rise in drip chamber **16** at a rate which exceeds the flow of the medicament into the conduit. This can be accomplished by adjustment of roller clamp **24**, such as by manipulating adjustment wheel **25** or, as is contemplated by the preferred embodiment, through termination end vent **72** formed in front wall **73** of termination end cap **70**. Thus, if roller clamp **24** is in its fully opened state, the narrow opening of termination end vent **72** will restrict liquid flow in conduit **20** to a rate which is slower than the rate that the medicament enters drip chamber **16** so that reservoir **64** can form in drip chamber **16** and so that fluid will enter conduit **20** at a slow rate to prevent the formation of air bubbles in conduit **20**. (page 16, lines 10-22).

Termination end cap **70** includes a termination end vent plug **74** which includes the same or a similar type of wettable, sealable, material of which vent plug **62** is made so that it seals when wetted by the solution. By placing this end plug at the termination end of the patient conduit, the conduit may be purged of any gas bubbles therein before use, and then sealed once the liquid solution reaches the termination end vent plug. (page 18, lines 1-9). Since any entrapped gas in the conduit may be easily purged therefrom, and then, once the solution wets the termination end vent plug (meaning that the gas has been removed) the end cap is sealed, the conduit, too, may be self-

primed without user intervention. This feature is likewise not shown in the art applied by the Examiner.

Respectfully submitted,
COHEN PONTANI LIEBERMAN & PAVANE LLP

By /Edward M. Weisz/
Edward M. Weisz
Reg. No. 37,257
551 Fifth Avenue, Suite 1210
New York, New York 10176
(212) 687-2770

Dated: January 27, 2010